Treatment of Anal Incontinence by an Implantable Prosthetic Anal Sphincter

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Twelve patients with anal incontinence due to neurologic disease or failure of previous incontinence surgery underwent implantation of an artificial anal sphincter. The system used was a modification of the AMS 800 artificial urinary sphincter. In two patients, infection necessitated removal of the system, and in four patients, eight revisional procedures had to be performed because of mechanical failure. After various modifications of the system, especially reinforcement of the closing mechanism of the cuff, only one case of mechanical failure has occurred. Erosion through the anal canal did not occur. Among 10 patients with the system in function for more than 6 months, the result was considered excellent in 5, with only occasional leakage of flatus, good in 3, who occasionally leaked liquid feces and flatus, and acceptable in 2, in whom the cuff obstructed defecation. It is concluded that implantation of an artificial anal sphincter is a valid alternative to permanant colostomy in patients with anal incontinence due to neurologic disorders and in patients in whom other types of incontinence surgery have failed.

SUCCESSFUL SURGICAL TREATMENT of traumatic anal incontinence has been achieved in approximately 80% of patients by reconstruction of the sphincter and pelvic floor muscles,[1,2] whereas long-term results in patients with idiopathic incontinence have been less satisfactory.[3] In patients with severe destruction of the external anal sphincter or failure of local repair, transposition of skeletal muscle (mainly gracilis or gluteus maximus) has been carried out with acceptable results,[4,5] which have recently been considerably improved by the simultaneous implantation of a neuromuscular stimulator.[6,7]

Anal incontinence due to neuromuscular disorders has not until recently been within the range of surgical or other forms of treatment. We recently reported the first successful implantation of an artificial sphincter for anal incontinence in a patient with a neurologic disease.[8] We report herein the results of the first 12 consecutive implantations.

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Materials and Methods

The artificial sphincter used is a modification of the AMS 800 artificial urinary sphincter (American Medical Systems [AMS], Minneapolis, MN). It consists of three parts (Fig. 1): a cuff placed around the anal canal, a pressure-regulating balloon, and a pump placed in the scrotum or labium majus with which the patient can inflate and deflate the cuff. The cuff is available in lengths of up to 14 cm and with maximum pressure of up to 90 cm H_2O.

Preoperative bowel preparation was performed by whole-gut irrigation, and the operation was performed with the patient in the lithotomy position. Two vertical incisions, each approximately 3 cm long, were made around the anal canal at 3 and 9 o'clock and a tunnel was created around the anal canal by blunt dissection. Pulleys were created posteriorly using the anococcygeal raphe and anteriorly using the raphe of the transversus perinei muscle. This ensured that the cuff would remain in the correct position around the anal canal. The pump was placed in the scrotum or labium majus, and the pressure-regulating balloon extraperitoneally on the left side of the bladder.

Finally, the three components were connected through subcutaneous tunnels with Silastic tubings. Defunctioning enterostomy was not used. Antibiotic prophylaxis with cefuroxime 750 mg, metronidazole 500 mg, and clindamycin 600 mg was instituted on induction of anesthesia and continued with three daily doses for 8 days. During the first 3 to 4 weeks after the operation, the system was left deactivated with the cuff permanently deflated. The patients were kept on a liquid elementary diet for 8 days.

All the patients, in whom the implantation was the only alternative to a permanent colostomy, gave their consent after being informed of the experimental nature of the procedure, including the risk of infection.

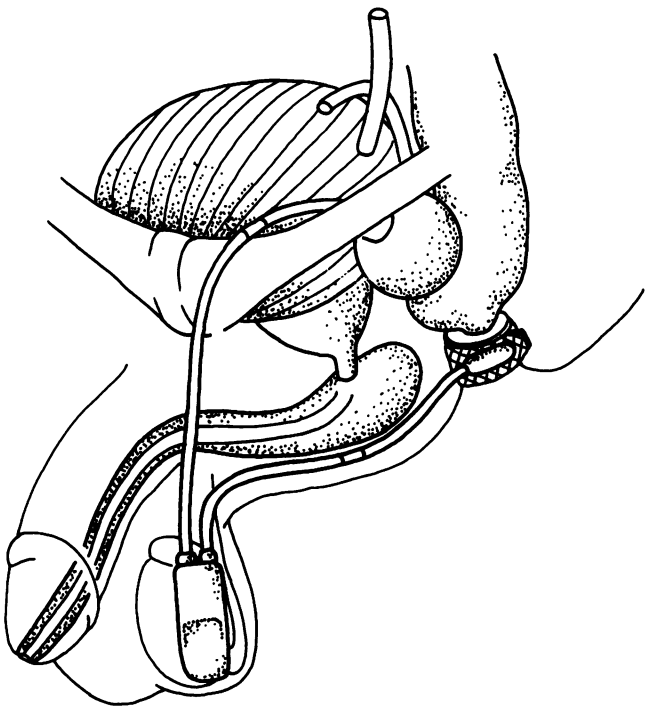

FIG. 1. The artificial anal sphincter in position. The cuff is placed around the anal canal, the pressure-regulating balloon to the left of the bladder, and the pump (control assembly) in the scrotum.

Twelve patients, 9 women and 3 men with ages ranging from 25 to 68 years and suffering from total anal incontinence due mainly to neurologic disorders, had a modified AMS sphincter implanted (Table 1). Nine patients were incontinent because of neurologic disorders. One (with cerebral trauma) had been operated on for anal atresia in childhood with an unsatisfactory result. After cerebral trauma, he had become completely incontinent. One of the three patients with failed previous surgery was still incontinent despite both a previous local sphincter repair and a gracilis transposition.

The median follow-up period was 19 months (range, 6 to 34 months). Preoperative anorectal physiologic parameters are shown in Table 2, together with control values from our laboratory.[9]

Results

The technical results of the implantation are shown in Table 3. Two patients developed infection that necessitated removal of the device 11 and 20 days, respectively, after implantation. One of these patients had the antibiotic prophylaxis discontinued after 3 days because of nausea and vomiting. The other, a young man with chronic nephritis and generalized neuropathy who had refused colostomy, was under immunosuppressive treatment.

Revisional surgery for mechanical failure of the system (rupture of the cuff and balloon) had to be performed 8 times in four patients, finally resulting in removal of the device in two. These two patients would have required yet another revision (revision numbers 3 and 4, respectively) due to repeated rupture of the cuff, but at that stage they preferred a permanent colostomy instead. In one patient, infection at the pump site occurred 6 months after implantation. At that time, the patient was receiving prednisone 40 mg daily because of his primary disease (myasthenia gravis). The pump was reimplanted on the opposite side, after which no further infection developed. Erosion of the cuff into the anal canal did not occur in any patient.

The clinical results in the 10 patients in whom the system has been in function for more than 6 months are shown in Table 4. Five patients were completely continent with only occasional leakage of flatus and no obstruction of defecation. Three patients leaked flatus and occasionally liquid feces as well. In two patients with irritable bowel syndrome and frequent periods of constipation, obstruction defecation necessitated frequent use of laxatives and enemas. This was due to the cuff, which in both patients was 10 cm long. One of these patients also leaked fluid feces periodically. Both patients, however, preferred the artificial sphincter to their preoperative condition.

TABLE 1. *Underlying Disorders That Cause Anal Incontinence Necessitating Implantation of Artificial Sphincter*

Anal incontinence due to neurologic disorder	9
Prolapsed intervertebral disc	3
Benign spinal tumor	1
Diabetic neuropathy	1
Polyneuropathy	2
Cerebral trauma	1
Myasthenia gravis	1
Failure of previous therapy for anal incontinence	3

TABLE 2. *Preoperative Anorectal Physiologic Parameters*

	Patients	Control value
Anal resting pressure (cm H_2O)	5–20	46–98
Anal squeeze pressure (cm H_2O)	10–48	78–234
Maximum tolerable rectal volume (mL)	100–450	175–450
Pudendal nerve terminal latency (msec)*	2.6–4.8	<2.2

* Examined in only 7 patients with neurologic disease.

TABLE 3. *Technical Result of Implantation of Artificial Sphincter*

Early removal of system	2
Revisional surgery (no. of procedures)	8
Median period with system in function (mo)	19 (6–35)

TABLE 4. *Clinical Result of Implantation of Artificial Anal Sphincter in 10 Patients With the System in Function More Than 6 Months*

Excellent	5
Good	3
Acceptable	2
Total	10

Anal canal pressure with the cuff deflated and inflated was 5 to 38 and 40 to 82 cm H_2O, respectively. Defecography with the cuff open and closed was performed in nine patients, demonstrating an anorectal angle of less than 90° with the cuff inflated (Table 5). There was no leakage of the semisolid contrast medium during straining. An example is shown in Figure 2.

Discussion

Implantation of an artificial sphincter for anal incontinence should be considered as an alternative to permanent colostomy. These preliminary results demonstrate that the technique can provide satisfactory function even after long-term follow-up and that the complications most feared, namely infection and erosion, can be controlled. Furthermore, the implantation can be performed without a protective colostomy when adequate bowel cleansing and antibiotic prophylaxis are used.

The high frequency of revisional surgery due to mechanical failures of the system (mainly rupture of the closing tab of the cuff) was limited to the first part of the study, where the unmodified urinary sphincter (AMS 800) was used. After modification of the system for use as an anal sphincter, which included longer and higher cuffs (up to 14 cm in length and 2.5 cm high), higher-pressured balloons (84 to 90 cm H_2O), and stronger closing tabs of the cuff, mechanical failure has only occurred once. Because some diffusion of fluid from the system may take place, another technical advantage has been the construction of a septum pump, which allows refilling of fluid into the system by percutaneous puncture.

Some technical details are important for a satisfactory outcome. It is essential that the cuff is kept in place around the anal canal and does not slide down against the perineal skin, because this will compromise its effect on the anal canal and possibly result in erosion through the skin. This is accomplished by placing the cuff above the anococcygeal raphe posteriorly and above the corresponding raphe anteriorly. If the latter is not present, it may be substituted by the tendinous part of the transversus perinei muscle. In the patient with anal atresia, it was possible to place the cuff above a rudimentary puborectalis muscle.

Erosion of the cuff into the anal canal did not occur in any patient. This is possibly because the cuff was placed around the sphincter muscles, which, in all patients except one, were anatomically intact and thereby constituted a protective layer around the anal canal. In the patient with anal atresia who had no such protective muscles, a layer of fascia from the anterior rectus sheet was encircled around the bowel before placing the cuff. This patient has been followed for 30 months with no sign of erosion. The fact that the anal canal pressure with the cuff inflated was constantly lower than the cuff pressure indicates that the compression force of the cuff is absorbed partially by the muscles and connective tissue around the anal canal.

As in other forms of surgery for anal incontinence, the outcome cannot be correlated convincingly to the anal canal pressure obtained postoperatively with the cuff inflated.[10] Defecography with the cuff deflated and inflated suggests the importance of an obtuse anorectal angle during inflation that act as a flap valve.

The present modification of the artificial sphincter seems to have overcome the initial mechanical problems that necessitated repeated revisional procedures. There should now be no reason to believe that the risk of mechanical failure will be different from that seen with the artificial urologic sphincter, which is at present lower than 5%.[11]

TABLE 5. *Relationship Between Clinical Results and Anal Canal Pressure and Anorectal Angle With the Cuff Deflated/Inflated*

	Clinical Result		
	Excellent	Good	Acceptable
Anal canal pressure (mmHg)	10–22/62–82	5–38/40–74	8–26/48–68
Anorectal angle (°)	105–120/72–85	100–125/72–85	108–130/80–88

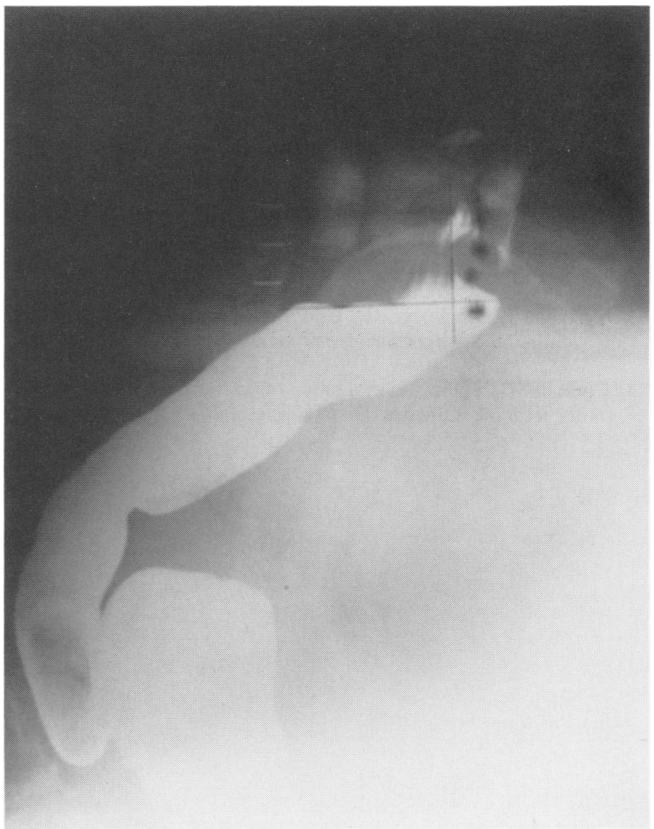

FIG. 2. Defecography during maximum straining with the cuff inflated. The anorectal angle is maintained at approximately 90°.

In conclusion, these preliminary results indicate that implantation of an artificial sphincter is a valid alternative to permanent colostomy in patients with anal incontinence due to neuromuscular disease.

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